DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

September 10, 2001

WARNING LETTER
CHI-48-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David J. Lang, President
Lang Dental Manufacturing Co., Inc.
175 Messner Drive
Wheeling, IL 60090

Dear Mr. Lang:

During an inspection of your firm, from April 10 to April 13, 2001, Investigator Tamara Brey determined that your establishment manufactures dental acrylics, resins, and reliners. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. For example, seven out of [redacted] batches of Flexacryl Hard/Soft Liquid were formulated to volumes not specified in the Mixing Formulas FL-0942 procedure dated March 19, 2001, and the Soft Acrylic Liquid Mixing Formula, dated February 6, 1995. These two procedures are specified in the Device Master Record for Flexacryl.

2. Failure to maintain the Device Master Record for Flexacryl. For example, the labeling specifications for Flexacryl kits were not current.

3. Failure to maintain the Device History Record (DHR) for Flexacryl products. For example, the Packaging and Labeling Control LDF 003 WP1297 in the Flexacryl DHR did not contain the primary identification or labeling used for each production batch.

4. Failure to establish and maintain corrective and preventive action procedures that include requirements for:

4.1. Analyzing, trending, and evaluation quality data such as complaints, returned product, nonconforming products and nonconforming work operations;
4.2. Verifying and/or validating the corrective and preventive action to ensure that such action does not adversely affect the finished device.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act, in that your firm failed to establish medical device reporting procedures as required by the Medical Device Reporting (MDR) Regulation, as specified in 21 CFR Part 803.

We acknowledge receipt of your firm's responses dated May 3 and July 13, 2001, from Ms. Joanne B. Lang, Quality Director, to our FDA-483, dated April 13, 2001. We have reviewed your response and find that it is inadequate because the response dated July 13, 2001, failed to explain how your SOP #36, Rev. 3, Corrective and Preventive Action Procedure:

1. Analyzes, trends, and evaluates quality data such as complaints, returned product, nonconforming products and nonconforming work operations;
2. Requires verifying and/or validating the corrective and preventive action to ensure that such action does not adversely affect the finished device.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer, at the above address.

Sincerely yours,

\s\
Raymond V. Mlecko
District Director